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Dated: September 13, 2010
Electronic Signature for Elizabeth A. Hanley: /Elizabeth A. Hanley/

APPENDIX - B

Docket No. 117750-01801
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Kenneth Powell *et al.*

Confirmation #: 2807

Application No. 10/593,666

Filed: March 12, 2007

Art Unit: 1627

For: **PHARMACEUTICAL COMPOSITION COMPRISING A BENZODIAZEPINE DERIVATIVE AND AN INHIBITOR OF THE RSV FUSION PROTEIN**

Examiner: PIHONAK, Sarah

MS RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR CONTINUED EXAMINATION (RCE) UNDER 37 C.F.R. § 1.114 AND RESPONSE TO FINAL OFFICE ACTION

Dear Sir:

In response to the Final Office Action dated June 14, 2010 (Paper No.: 20100608), Applicant hereby submits this Request for Continued Examination (RCE) and Response and Amendment. Please amend the above-identified U.S. patent application as indicated below.

Amendment to the Claims begin on page 2 of this paper.

Remarks begin on page 23 of this paper.

Amendments to the Claims

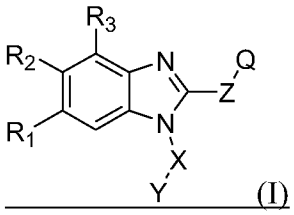
This claim set replaces all previous claims in this application.

1. (Currently amended) A pharmaceutical composition which comprises a pharmaceutically acceptable carrier or diluent and:

(a) an inhibitor of the RSV fusion protein; and

(b) a benzodiazepine derivative capable of inhibiting RSV replication

wherein component (a) is a compound of formula (I), or a pharmaceutically acceptable salt thereof,



(I)

wherein:

X is a direct link or C_{1-6} alkyl; said C_{1-6} alkyl being optionally substituted with halogen, oxo, cyano, $OCOR_4$ or $S(O)_n$-C_{1-6} alkyl;

Y is R_4, NR_4R_5, $NCOR_4$, =N-OR_4, -$CONHR_4$, $COOR_4$, -OR_4, aryl, heteroaryl, cyclyl or heterocyclyl, where R_4 and R_5 are H or C_{1-6} alkyl;

Z is CR_6R', where R_6 is H, or straight, branched or cyclic C_{1-6} alkyl and R' is straight, branched or cyclic C_{1-6} alkyl;

n is 1-2;

R_1 is H, $CONR_4R_5$, CO_2R_4 or C_{1-6} alkyl, said C_{1-6} alkyl can be optionally substituted with OR_4 or NR_8R_9;

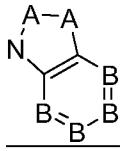
R_8 and R_9 are each independently H, C_{1-6} alkyl, SO_2R_5, CO_2R_4 or COR_4;

R_2 is selected from the group consisting of H, NH_2, $CONR_6R'$, heteroaryl, C_{2-6} alkenyl, CO_2R_4, $N=CPh_2$, $C(=NH)NH_2$ and C_{1-6} alkyl; said alkyl optionally substituted with a member selected from the group consisting of halogen, CN, $NR_{10}R_{11}$, OSO_2R_4 and OR_4;

R_{10} and R_{11} are each independently selected from the group consisting of H, C_{1-6} alkyl, C_{3-6} cycloalkyl, CO_2R_4, COR_4 and SO_2R_4;

R_3 is selected from the group consisting of (1) CO_2R_9; (2) C_{1-6} alkyl optionally substituted with CN, OR_4 or NR_6R'; (3) H; and (4) C_{2-6} alkenyl substituted with CN;

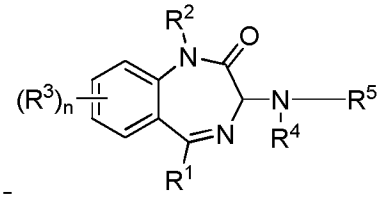
Q is a member selected from the group consisting of



A is C or N, optionally substituted with H, halogen, C_{1-6} alkyl, C_{2-6} alkenyl, cyano-C_{1-6} alkyl, CO_2R_4, aryl, benzoaminocarbonyl, hydroxybenzyl, $SO_2NR_4R_5$ or C_{3-6} cycloalkyl. Where A is carbon, it may also be optionally substituted by O or S via a double bond;

B is C or N; where B is C it may be optionally substituted by H, C_{1-6} alkyl, NO_2, CN, halogen, COR_4, $COOR_4$, $CONHR_4C(=NH)NH_2$ or $C(=N0H)NH_2$.

2. (Previously presented) A composition according to claim 1, wherein component (b) is a compound of formula (V), or a pharmaceutically acceptable salt thereof,



(V)

wherein:

R^1 represents C_{1-6} alkyl, aryl or heteroaryl;

R^2 represents hydrogen or C_{1-6} alkyl;

each R^3 is the same or different and represents halogen, hydroxy, C_{1-6} alkyl, C_{1-6} alkoxy, C_{1-6} alkylthio, C_{1-6} haloalkyl, C_{1-6} haloalkoxy, amino, mono(C_{1-6} alkyl)amino, di(C_{1-6} alkyl)amino, nitro, cyano, -CO_2R', -CONR'R'', -NH-CO-R', -S(O)R', -$S(O)_2$R', -NH-$S(O)_2$R', -S(O)NR'R" or -$S(O)_2$NR'R", wherein each R' and R" is the same or different and represents hydrogen or C_{1-6} alkyl;

n is from 0 to 3;

R^4 represents hydrogen or C_{1-6} alkyl;

R^5 represents C_{1-6} alkyl, aryl, heteroaryl, carbocyclyl, heterocyclyl, aryl-(C_{1-6} alkyl)-, heteroaryl-(C_{1-6} alkyl)-, carbocyclyl-(C_{1-6} alkyl)-, heterocyclyl-(C_{1-6} alkyl)-, aryl-(C_{1-6}

hydroxyalkyl)-, heteroaryl-(C_{1-6} hydroxyalkyl)-, carbocyclyl-(C_{1-6} hydroxyalkyl)-, heterocyclyl-(C_{1-6} hydroxyalkyl)-, aryl-C(O)-C(O)-, heteroaryl-C(O)-C(O)-, carbocyclyl-C(O)-C(O)-, heterocyclyl-C(O)-C(O)- or -XR^6;

X represents -CO-, -S(O)- or -$S(O)_2$-; and

R^6 represents C_{1-6} alkyl, hydroxy, C_{1-6} alkoxy, C_{1-6} alkylthio, aryl, heteroaryl, carbocyclyl, heterocyclyl, aryl-(C_{1-6} alkyl)-, heteroaryl-(C_{1-6} alkyl)-, carbocyclyl-(C_{1-6} alkyl)-, heterocyclyl-(C_{1-6} alkyl)-, aryl-(C_{1-6} alkyl)-O-, heteroaryl-(C_{1-6} alkyl)-O-, carbocyclyl-(C_{1-6} alkyl)-O-, heterocyclyl-(C_{1-6} alkyl)-O- or -NR'R" wherein each R' and R" is the same or different and represents hydrogen, C_{1-6} alkyl, carbocyclyl, heterocyclyl, aryl, heteroaryl, aryl-(C_{1-6} alkyl)-, heteroaryl-(C_{1-6} alkyl)-, carbocyclyl-(C_{1-6} alkyl)- or heterocyclyl-(C_{1-6} alkyl)-.

3. (Original) A composition according to claim 2 wherein:

each R^3 is the same or different and represents halogen, hydroxy, C_{1-6} alkyl, C_{1-6} alkoxy, C_{1-6} alkylthio, C_{1-6} haloalkyl, C_{1-6} haloalkoxy, amino, mono(C_{1-6} alkyl)amino, di(C_{1-6} alkyl)amino, nitro, cyano, -CO_2R', -CONR'R", -NH-CO-R', -S(O)R', -$S(O)_2$R', -NH-$S(O)_2$R' or -S(O)NR'R", wherein each R' and R" is the same or different and represents hydrogen or C_{1-6} alkyl ;

R represents C_{1-6} alkyl, aryl, heteroaryl, carbocyclyl, heterocyclyl, aryl-(C_{1-6} alkyl)-, heteroaryl-(C_{1-6} alkyl)-, carbocyclyl-(C_{1-6} alkyl)-, heterocyclyl-(C_{1-6} alkyl)- or -XR^6;

X represents -CO-, -S(O)- or -$S(O)_2$-; and

R^6 represents C_{1-6} alkyl, hydroxy, C_{1-6} alkoxy, C_{1-6} alkylthio, aryl, heteroaryl, carbocyclyl, heterocyclyl, aryl-(C_{1-6} alkyl)-, heteroaryl-(C_{1-6} alkyl)-, carbocyclyl-(C_{1-6} alkyl)-, heterocyclyl-(C_{1-6} alkyl)- or -NR'R" wherein each R' and R" is the same or different and represents hydrogen, C_{1-6} alkyl, carbocyclyl, heterocyclyl, aryl, heteroaryl, aryl-(C_{1-6} alkyl)- or heteroaryl-(C_{1-6} alkyl)-.

4. (Previously presented) A composition according to claim 2, wherein R^1 is C_{1-2} alkyl or aryl.

5. (Previously presented) A composition according to claim 2 wherein R^2 is hydrogen.

6. (Previously presented) A composition according to claim 2 wherein R^3 is halogen, hydroxy, C_{1-4} alkyl, C_{1-4} alkoxy, C_{1-4} alkylthio, C_{1-4} haloalkyl, C_{1-4} haloalkoxy, amino, mono(C_{1-4} alkyl)amino or di(C_{1-4} alkyl)amino.

7. (Original) A composition according to claim 6, wherein R^3 is fluorine, chlorine, bromine, C_{1-2} alkyl, C_{1-2} alkoxy, C_{1-2} alkylthio, C_{1-2} haloalkyl, C_{1-2} haloalkoxy, amino, mono(C_{1-2} alkyl)amino or di (C_{1-2} alkyl)amino.

8. (Previously presented) A composition according to claim 2 wherein R^4 is hydrogen or C_{1-2} alkyl.

9. (Previously presented) A composition according to claim 2 wherein R^5 is C_{1-6} alkyl, aryl, heteroaryl, carbocyclyl, heterocyclyl, aryl-(C_{1-4} alkyl)-, heteroaryl-(C_{1-4} alkyl)-, carbocyclyl-(C_{1-4} alkyl)-, heterocyclyl- C_{1-4} alkyl)-, aryl-C(O)-C(O)-, heteroaryl-C(O)-C(O)- or -XR^6.

10. (Original) A composition according to claim 9, wherein R^5 is C_{1-4} alkyl, aryl, heteroaryl, carbocyclyl, heterocyclyl, phenyl-(C_{1-2} alkyl)-, heteroaryl-(C_{1-2} alkyl)-, phenyl-C(O)-C(O)-, heteroaryl-C(O)-C(O)- or -XR^6.

11. (Original) A composition according to claim 10, wherein R^5 is C_{1-4} alkyl, phenyl, thienyl, furanyl, isoxazolyl, pyridyl, cyclopentyl, cyclohexyl, benzothienyl, dihydrobenzofuranyl, phenyl-CH_2-, furanyl-CH_2-, phenyl-C(O)-C(O)-, thienyl-C(O)-C(O)- or -XR^6.

12. (Previously presented) A composition according to claim 2 wherein, X is -CO- or -$S(O)_2$-.

13. (Previously presented) A composition according to claim 2 wherein, when R^6 is a group NR'R" wherein each R' and R" is the same or different and represents hydrogen, C_{1-4} alkyl, aryl, carbocyclyl, heterocyclyl, aryl-(C_{1-4} alkyl)- or heteroaryl-(C_{1-4} alkyl)-.

14. (Original) A composition according to claim 13, wherein when R^6 is a group –NR'R" each R' and R" is the same or different and represents hydrogen, C_{1-4} alkyl, phenyl, thienyl, cyclohexyl, cyclopentyl or phenyl-CH_2-.

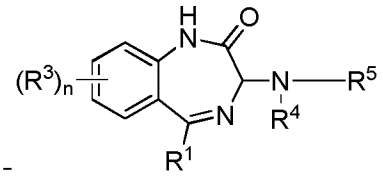
15. (Original) A composition according to claim 14, wherein when R^6 is a group –NR'R" and one of R' and R" is hydrogen.

16. (Previously presented) A composition according to claim 2 wherein R^6 is C_{1-6} alkyl, hydroxy, C_{1-6} alkoxy, C_{1-6} alkylthio, aryl, heteroaryl, carbocyclyl, heterocyclyl, aryl-(C_{1-4} alkyl)-, heteroaryl-(C_{1-4} alkyl)-, carbocyclyl-(C_{1-4} alkyl)-, heterocyclyl-(C_{1-4} alkyl)-, aryl-(C_{1-4} hydroxyalkyl)-, heteroaryl-(C_{1-4} hydroxyalkyl)-, carbocyclyl-(C_{1-4} hydroxyalkyl)-, heterocyclyl-(C_{1-4} hydroxyalkyl)-, aryl-(C_{1-4} alkyl)-O-, heteroaryl-(C_{1-4} alkyl)-O-, carbocyclyl-(C_{1-4} alkyl)-O-, heterocyclyl-(C_{1-4} alkyl)-O- or –NR'R".

17. (Original) A composition according to claim 16, wherein R^6 is C_{1-6} alkyl, C_{1-6} alkoxy, C_{1-6} alkylthio, aryl, heteroaryl, carbocyclyl, heterocycly, phenyl-(C_{1-2} alkyl)-, phenyl-(C_{1-2} alkyl)-O-, heteroaryl-(C_{1-2} alkyl)-, phenyl-(C_{1-2} hydroxyalkyl)-, heteroaryl-(C_{1-2} hydroxyalkyl)- or -NR'R".

18. (Original) A composition according to claim 17, wherein R^6 is C_{1-4} alkyl, C_{1-4} alkoxy, phenyl, naphthyl, dihydrobenzofuranyl, benzodioxinyl, 9H-fluoren-9-onyl, indolyl, thienyl, furanyl, oxazolyl, isoxazolyl, pyrazolyl, pyridyl, benzothienyl, benzofuranyl, cyclopentyl, cyclohexyl, piperazinyl, piperidinyl, morpholinyl, phenyl-(C_{1-2} alkyl)-, phenyl-CH_2-CH(OH)-, phenyl-CH(OH)-CH_2-, phenyl-(C_{1-2} alkyl)-O-, 1H-benzo[d]imidazol-2(3H)-onyl or –NR'R".

19. (Previously presented) A composition according to claim 2 wherein the benzodiazepine derivative of formula (V) is a benzodiazepine derivative of formula



(Va):

wherein:

R^1 is phenyl or methyl;

R^3 is methyl or chlorine;

n is 0 or 1;

R^4 is hydrogen or methyl;

R^5 is phenyl-CH_2-, furanyl-CH_2-, thienyl-C(O)-C(O)- or -XR^6;

X is -CO- or -$S(O)_2$-; and

R^6 is C_{1-4} alkyl, C_{1-4} alkoxy, phenyl, naphthyl, dihydrobenzofuranyl, benzodioxinyl, 9H-fluoren-9-onyl, indolyl, thienyl, furanyl, oxazolyl, isoxazolyl, pyrazolyl, pyridyl, benzothienyl, benzofuranyl, cyclopentyl, cyclohexyl, piperazinyl, piperidinyl, morpholinyl, phenyl-(C_{1-2} alkyl)-, phenyl-CH_2-CH(OH)-phenyl-CH(OH)-CH_2-, phenyl-(C_{1-2} alkyl)-O-, lH-benzo[d]imidazol-2(3H)-onyl or -NR'R" wherein each R' and R" is the same or different and represents hydrogen, C_{1-4} alkyl, phenyl, thienyl, cyclohexyl, cyclopentyl or phenyl-(CH_2)-, the phenyl moiety in the group R^1 being unsubstituted or substituted by a single fluorine, chlorine, C_{1-2} alkyl, C_{1-2} alkoxy, C_{1-2} alkylthio, C_{1-2} haloalkyl or C_{1-2} haloalkoxy substituent;

the aryl moieties in the groups R^5 and R^6 being unsubstituted or substituted by 1, 2 or 3 substituents selected from fluorine, chlorine, bromine, iodine, C_{1-4} alkyl, C_{2-4} acyl, hydroxy, C_{1-4} alkoxy, C_{1-4} alkylthio, C_{1-4} haloalkyl, C_{1-4} haloalkoxy, amino, mono(C_{1-4} alkyl)amino, di(C_{1-4} alkyl)amino, nitro, -CO_2R', -$S(O)_2$R' and -$S(O)_2NH_2$, wherein R' represents C_{1-2} alkyl;

the heteroaryl moieties in the groups R^5 and R^6 being unsubstituted or substituted by 1 or 2 substituents selected from fluorine, chlorine, bromine, C_{1-2} alkyl, C_{1-2} haloalkyl and di(C_{1-2} alkyl)amino; and

the heterocyclyl and carbocyclyl moieties in the R^6 group being unsubstituted or substituted by 1 or 2 substituents selected from fluorine, chlorine, bromine, C_{1-4} alkyl, C_{1-4} alkoxy, C_{1-4} haloalkyl and nitro.

20. (Original) A composition according to claim 1, wherein the benzodiazepine derivative of formula (V) is:

Cyclohexanecarboxylic acid 2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-amide;

3-Methoxy N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1 ,4]diazepin-3-yl)-benzamide;

4-Methoxy N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

2-Methoxy N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

N-(2-Oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-3-trifluoromethyl-benzamide;

N-(2-Oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-benzamide;

Thiophene-2-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4] diazepin-3-yl)-3-amide;

Furan-2-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4] diazepin-3-yl)-amide;

Piperidine-1-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4] diazepin-3-yl)-amide;

Morpholine-4-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4] diazepin-3 -yl)-amide;

4-Nitro-N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-benzamide;

3-Nitro-N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-benzamide;

4-Methyl-piperazine-l-carboxylic acid-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-amide;

3,4-Dichloro-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-2-trifluoromethyl-benzamide;

4-Bromo-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

2-Methyl-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

2-Chloro-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

2-Nitro-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

2-Methoxy-4-nitro-N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-benzamide;

(S)-2-Methoxy-4-nitro-N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4] diazepin-3-yl)-benzamide

Benzo[b]thiophene-3-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-l H-benzo[e] [1,4]diazepin-3-yl)-amide;

2,3-Dihydro-benzofuran-5-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][l,4]diazepin-3-yl)-amide;

Isoxazole-5-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4] diazepin-3-yl)-amide;

Benzo[b]thiophene-2-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-amide;

Thiophen-3-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4] diazepin-3-yl)-amide;

N-(2-Oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4] diazepin-3-yl)-isonicotinamide;

N-(2-Oxo-5 -phenyl-2,3-dihydro-1 H-benzo [e][1,4] diazepin-3-yl)-nicotinamide;

N-(2-Oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4] diazepin-3-yl)-methanesulfonamide;

Propane-1-sulfonic acid-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4] diazepin-3-yl)-amide;

Butane-l-sulfonic acid-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-amide;

2-Bromo-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzenesulfonamide;

3-Bromo-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzenesulfonamide;

4-Bromo-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzenesulfonamide;

2-Fluoro-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzenesulfonamide;

3-(2-Nitro-benzylamino)-5-phenyl-1,3-dihydro-benzo[e][1,4]diazepin-2-one;

3-(3-Nitro-benzylamino)-5-phenyl-l,3-dihydro-benzo[e][l,4]diazepin-2-one;

3-(4-Nitro-benzylamino)-5-phenyl-1,3-dihydro-benzo[e][1,4]diazepin-2-one;

3-(2-Methoxy-benzylamino)-5-phenyl-1,3-dihydro-benzo[e][1,4]diazepin-2-one;

3-(3-Methoxy-benzylamino)-5-phenyl-l,3-dihydro-benzo[e][l,4]diazepin-2-one;

5-Phenyl-3-(2-trifluoromethyl-benzylamino)-l,3-dihydro-benzo[e][l,4]diazepin-2-one;

5-Phenyl-3-(3-trifluoromethyl-benzylamino)-1,3-dihydro-benzo[e][1,4]diazepin-2-one;

5-Phenyl-3-(4-trifluoromethyl-benzylamino)-1,3-dihydro-benzo[e][l,4]diazepin-2-one;

3-[(Furan-2-ylmethyl)-amino]-5-phenyl-l,3-dihydro-benzo[e][l,4]diazepin-2-one;

N-(7-Chloro-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-acetamide;

N-(7-Chloro-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-isobutyramide;

N-(7-Chloro-2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-methanesulfonamide;

Furan-2-carboxylic acid (7-chloro-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4] diazepin-3-yl)-amide;

Thiophene-2-carboxylic acid (7-chloro-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e] [1,4]diazepin-3-yl)-amide;

Cyclohexanecarboxylic acid (7-Chloro-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e] [1,4]diazepin-3-yl)-amide;

N-(7-Chloro-2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-2-methoxy-benzamide;

N-(7-Chloro-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-4-methoxy-benzamide;

N-(7-Chloro-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-2-nitro-benzamide;

2-(2-Methoxy-phenyl)N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4] diazepin-3-yl)-acetamide;

2-(3-Methoxy-phenyl)N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4] diazepin-3-yl)-acetamide;

2-(4-Methoxy-phenyl)N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4] diazepin-3-yl)-acetamide;

2-(4-Nitro-phenyl)N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-acetamide;

2-(3-Nitro-phenyl)N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-acetamide;

N-(2-Oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-2-(2-trifluoromethyl-phenyl)-acetamide;

N-(2-Oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-2-(3-trifluoromethyl-phenyl)-acetamide;

N-(2-Oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-2-(4-trifluoromethyl-phenyl)-acetamide;

l-(2-Methoxy-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4] diazepin-3-yl)-urea;

l-(2-Nitro-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-urea;

1-(2-Chloro-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1 ,4]diazepin-3-yl)-urea;

1-(4-Chloro-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl-urea;

1-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-3-p-tolyl-urea;

1-(2-Fluoro-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][1,4]diazepin-3-yl)-urea;

1-(4-Fluoro-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][1,4] diazepin-3-yl)-urea;

(S)-l-(2-Fluoro-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4] diazepin-3-yl)-urea;

4-Methanesulfonyl-2-methoxy-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e] [1,4]diazepin-3-yl)-benzamide;

(S)-4-Methanesulfonyl-2-methoxy-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

5-Acetyl-2-ethoxy-N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-benzamide;

(S)-5-Acetyl-2-ethoxy-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4] diazepin-3-yl)-benzamide;

6-Fluoro-4H-benzo[l,3]dioxine-8-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][1,4]diazepin-3-yl)-amide;

(S)-6-Fluoro-4H-benzo[l,3]dioxine-8-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-amide;

(S)-2-Methoxy-N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-4-trifluoromethyl-benzamide;

2,4,5-Trifluoro-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

(S)-2,4,5-Trifluoro-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

2-Hydroxy-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

(S)-2-Hydroxy-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

1H-Indole-7-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4] diazepin-3-yl)-amide;

(S)-1H-Indole-7-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][1,4]diazepin-3-yl)-amide;

3-Methoxy-naphthalene-2-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-amide;

(S)-3-Methoxy-naphthalene-2-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-amide;

N-[7-Chloro-5-(2-fluoro-phenyl)-2-oxo-2,3-dihydro-lH-benzo[e][l,4]diazepine-3-yl]-4-methoxoy-benzamide;

1-(2-Fluoro-benzyl)-3-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1 ,4]diazepin-3-yl)-urea;

1-(4-Methoxy-benzyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][1,4] diazepin-3-yl)-urea;

1-(3-Methyl-benzyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][1,4]diazepin-3-yl)-urea;

l-(2-Oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-3-(4-trifluoromethyl-phenyl)-urea;

4-Chloro-2-methoxy-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

4-Methoxy-3-nitro-N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)benzamide;

3-Methoxy-2-nitro-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

5-Chloro-2-methoxy-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)benzamide;

5-Fluoro-2-methoxy-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

2-Methoxy-4-nitro-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

5-Methoxy-2-nitro-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

3-Methoxy-4-nitro-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

3-(2-Methoxy-phenyl)-N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1 ,4]diazepin-3-yl)propionamide;

3-(3-Methoxy-phenyl)-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-propionamide;

3-(4-Methoxy-phenyl)-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-propionamide;

N-[5-(3-Chloro-phenyl)-2-oxo-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl]-2-methoxy-benzamide;

N-[5-(3-Chloro-phenyl)-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl]-4-methoxy-benzamide;

N-[5-(3-Chloro-phenyl)-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl]-2-nitro-benzamide;

N-[5-(3-Chloro-phenyl)-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl]-4-nitro-benzamide;

4-Methoxy-N-[2-oxo-5-(4-trifluoromethyl-phenyl)-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl]-benzamide;

2-Methoxy-N-[2-oxo-5-(3-trifluoromethyl-phenyl)-2,3-dihydro-lH-benzo[e][1,4]diazepin-3-yl]-benzamide;

4-Methoxy-N-[2-oxo-5-(3-trifluoromethyl-phenyl)-2,3-dihydro-lH-benzo[e][1,4]diazepin-3-yl]-benzamide;

2-Ethoxy-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][1,4]diazepin-3-yl)-benzamide;

2,4-Dimethoxy-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

2-Bromo-5-methoxy-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

2-Methoxy-N-[5-(3-mehtoxy-phenyl)-2-oxo-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl]-benzamide

N-[5-(3-Methoxy-phenyl)-2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1 ,4]diazepin-3-yl]-4-nitro-benzamide;

2-Methoxy-N-(8-methyl-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

2-Chloro-4-methanesulfonyl-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

2-Dimethylamino-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

(2-Oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-carbamic acid benzyl ester;

l-(3,5-Dimethyl-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4] diazepin-3-yl)-urea;

l-(2-Oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-3-(4-trifluoromethoxy-phenyl)-urea;

1-(4-Bromo-2-trifluoromethyl-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][l,4]diazepin-3-yl)-urea;

l-(4-Bromo-benzyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-urea;

l-(2,3-Dichloro-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3 -yl)-urea;

1-(2,6-Dimethyl-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][1,4]diazepin-3-yl)-urea;

l-(2-Chloro-6-methyl-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][1,4]diazepin-3-yl)-urea;

1-(4-Nitro-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-urea;

l-(2-Methylsulfanyl-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-urea;

l-(2,6-Dichloro-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4] diazepin-3-yl)-urea;

5-tert-Butyl-2-methoxy-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

2,5-Dimethoxy-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

1 -(2,6-Difluoro-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4] diazepin-3-yl)-urea;

l-(3-Fluoro-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-urea;

l-(3-Methoxy-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4] diazepin-3-yl)-urea;

l-(2-Oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-3-(3-trifluoromethyl-phenyl)-urea;

l-(3-Chloro-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e]1,4]diazepin-S-yl)-urea;

2-Methoxy-4-methylsulfanyl-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

4-Methanesulfonyl-N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-benzamide;

N-(2-Oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1 ,4]diazepin-3-yl)terephthalamic acid methyl ester;

2-Fluoro-N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-benzamide;

2,6-Difluoro-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide;

N-(2-Oxo-5-phenyl-2, 3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-2-propoxy-benzamide;

2-Iodo-N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1 ,4]diazepin-3-yl)-benzamide;

3-Methoxy-N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-terephthalamic acid methyl ester;

4-Amino-5-chloro-2-methoxy-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e] [1,4]diazepin-3-yl)-benzamide;

l-(2-Oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-3-m-tolyl-urea;

2-Methylsulfanyl-N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-benzamide;

2-Methoxy-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-5-sulfamoyl-benzamide;

2-Hydroxy-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-3-phenyl-propionamide

3-Hydroxy-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-3-phenyl-propionamide;

3-(2-Fluoro-phenyl)-l-methyl-1-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-urea;

2-Methoxy-N-methyl-4-nitro-N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-benzamide;

1-tert-Butyl-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-urea;

1-Cycloheyl-3-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-urea;

1-Ethyl-3-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-urea;

1-Butyl-3-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-urea;

4,5-Dimethyl-furan-2-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][1,4]diazepin-3-yl)amide;

Piperidine-1-carboxylic acid (7-chloro-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][1,4]diazepin-3-yl)-amide;

N-[5-(3-Chloro-phenyl)-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)acetamide;

N-[5-(3-Chloro-phenyl)-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl]-isobutyramide;

Furan-2-carboxylic acid [5-(3-chloro-phenyl)-2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][l,4]diazepin-3-yl]-amide;

Thiophene-2-carboxylic acid [5-(3-chloro-phenyl)-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl]-amide;

Cyclohexanecarboxylic acid [5-(3chloro-phenyl)-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl]-amide;

Piperidine-1-carboxylic acid [5-(3-chloro-phenyl)-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl]-amide;

N-[5-(3-Chloro-phenyl)-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl]isonicotinamide;

5-Methyl-furan-2-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e] [1,4] diazepin-3-yl)-amide;

Pyrazine-2-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4] diazepin-3-yl)-amide;

N-[5-(3-Methoxy-phenyl)-2-oxo-5-phenyl2,3-dihydro-lH-benzo[e][1,4]diazepin-3-yl]-isobutyramide;

Thiophene-2-carboxylic acid [5-(3-methoxy-phenyl)-2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl] -amide;

Cyclohexanecarboxylic acid [5-(3-methoxy-phenyl)-2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][l,4]diazepin-3-yl]-amide;

Piperidine-1-carboxylic acid [5-(3-methoxy-phenyl)-2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl]-amide;

Piperidine-4-carboxylic acid [5-(3-methoxy-phenyl)-2-oxo-5-phenyl-2,3-dihydro-1 H-benzo[e][l,4]diazepin-3-yl]-amide;

Cyclohexanecarboxylic acid (8-chloro-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e] [l,4]diazepin-3-yl)-amide;

Thiophene-2-carboxylic acid (8-methyl-2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-amide;

l-(2-Oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-3-thiophene-2-yl-urea;

1-(2-Oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1,4]diazepin-3-yl)-3-thiophene-3-yl-urea;

Pyridine-2 -carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l ,4] diazepin-3-yl)-amide;

1H-Pyrazole-4-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-l H-benzo[e] [1 ,4] diazepin-3-yl)-amide;

6-Dimethylamino-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-nicotinamide;

2-Ethoxy-naphthalene-l -carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-amide;

9-Oxo-9H-fluorene-l -carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e] [1,4]diazepin-3-yl)-amide;

2-Oxo-2,3-dihydro-benzoimidazole-l -carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][l,4]diazepin-3-yl)-amide;

(2-Oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)carbamic acid tert-butyl ester;

(S)-4,5-Dibromo-furan-2-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][1 ,4]diazepin-3-yl)-amide;

(S)-Benzofuran-2-carboxylic acid (2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e] [1 ,4]diazepin-3-yl)-amide;

(2-Oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-carbamic acid methyl ester;

(2-Oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l ,4]diazepin-3-yl)-carbamic acid ethyl ester;

(2-Oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-carbamic acid isobutyl ester; and

2-Oxo-N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1 ,4]diazepin-3-yl)-2-thiophene-2-yl-acetamide.

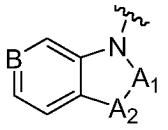
21. (Previously presented) A composition according to claim 2, wherein the benzodiazepine derivative of formula (V) is l-(2-fluoro-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-urea, 2-methoxy-4-nitro-N-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4]diazepin-3-yl)-benzamide or 4-methanesulfonyl-2-methoxy-N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo[e][1 ,4]diazepin-3 -yl)-benzamide.

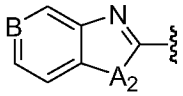
22. (Original) A composition according to claim 21, wherein the benzodiazepine derivative of formula (V) is l-(2-fluoro-phenyl)-3-(2-oxo-5-phenyl-2,3-dihydro-lH-benzo[e][l,4] diazepin-3-yl)-urea.

23. (Cancelled)

24. (Currently amended) A composition according to claim 1 ~~claim 23~~, wherein at least two of R_1, R_2 and R_3 are hydrogen, and the other is hydrogen or -C(NH)-NH_2 and/or either -X-Y is

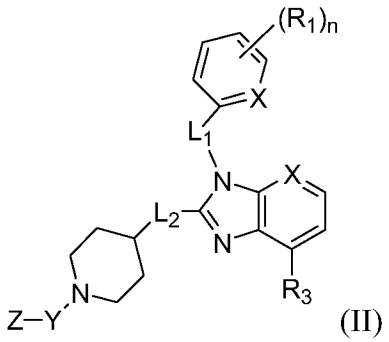
H, or X is a C_1-C_6 alkylene group which is unsubstituted or substituted by a hydroxy group and Y is H, OH, CN, -NR'R", -COR', -SO_2R' or phenyl, wherein R' and R" are the same or different and represent a C_1-C_4 alkyl group and/or Z is -CH_2- and/or Q is a moiety



or


wherein B is -CH- or -N-, A_1 is -C(O)- or -NH- and A_2 is -CH_2-, -CHR'- or –NR"-, wherein R' is a halogen atom and R" represents a hydrogen atom or a C_{1-4} alkyl, C_{2-4} alkenyl, C_{3-6} cycloalkyl, -SO_2-(C_{1-6} alkyl), -SO_2-N(C_{1-6} alkyl)$_2$ or -(CO-NH)$_a$-(C_{1-4} alkyl)-phenyl group, wherein a is 0 or 1, which group is unsubstituted or is substituted with a hydroxy or cyano substituent.

25. (Withdrawn) A composition according to claim 1, wherein component (a) is a compound of the formula (II), or a pharmaceutically acceptable salt thereof



(II)

wherein:

L_1 is -CH_2- or -CHR_2-CO-

each X is the same or different and is CH or N;

each R_1 is the same or different and is C_{1-6} alkyl, halogen, hydroxy, phenyl or $(CH_2)_m$=NH_2;

n is 1 or 2;

R2 is C_{1-6} alkoxy or C_{1-6} alkoxy-phenyl;

R3 is C_{1-6} alkyl;

L2 is -CH_2- or -NH-;

Y is C_{1-6} alkyl or C_{1-6} alkenyl;

Z is H, N(R_4)2-, -C(=O)-R_5, -C(=CH_2)-R_5, -CH(OH)-R_5, -CH(CH_3)-R_5, -CH(OCH_3)- R_5;

each R_4 is the same or different and is H, C1-6 alkyl.

R_5 is C_{1-6}alkyl-carbonyl, amino, hydroxyl, aryl, heteroaryl, carbocyclyl, heterocyclyl; and

m = 1-6

26. (Previously presented) A composition according to claim 1, wherein component (a) is:

l-Cyclopropyl-3-[1-(4-hydroxy-butyl)-lH-benzoimidazol-2-ylmethyl]-l,3-dihydro-imidazo[4, 5-c]pyridin-2-one

{2-[2-(l,2-Dihydro-benzotriazol-l-ylmethyl)-benzoimidazol-l-yl]]ethyl}-diethyl-amine

{2-[2-(3-Iodo-2,3-dihydro-indazol-l-ylmethyl)-benzimidazol-1-yl]-ethyl}-dimethyl-amine

1-Isopropenyl-3-[1-(3-methyl-butyl)-1H-benzoimidazol-2-ylmethyl]-l,3-dihydro-benzoimidazol-2-one

1-(4-Hydroxy-benzyl)-3-[1-(3-methyl-butyl)-lH-benzoimidazol-2-ylmethyl]-1,3-dihydro-benzoimidazol-2-one

l-Isopropenyl-3-[l-(3-oxo-butyl)-lH-benzoimidazol-2-ylmethyl]-l,3-dihydro-benzoimidazol-2-one

l-Ethyl-3-[l-(2-hydroxy-2-phenyl-ethyl)-lH-benzoimidazol-2-ylmethyl]-l,3-dihydro-benzoimidazol-2-one

l-Ethyl-3-[l-(4-hydroxy-butyl)-lH-benzoimidazol-2-ylmethyl]-l,3-dihydro-benzoimidazol-2-one

7-[2-(3-Isopropenyl-2-oxo-2,3-dihydrobenzoimidazol-l-ylmethyl)-benzoimidazol-l-yl]-heptanenitril

5-{3-[l-(3-Methanesulfonyl-propyl)-lH-benzoimidazol-2-ylmethyl]-2-oxo-2,3-dihydro-benzoimidazol-1-yl}-pentanenitrile

3-[l-(3-Methyl-buty)-lH-benzoimidazol-2-ylmethyl]-2-oxo-2,3-dihydro-benzoimidazol-1-carboxylic acid benzylamide

1-Methanesulfonyl-3-[1 -(3-methyl-butyl)-1H-benzoimidazol-2-ylmethyl]-1,3-dihydro-benzoimidazol-2-one

3-[1-(3-Methyl-butyl)-1H-benzoimidazol-2-ylmethyl]-2-oxo-2,3-dihydro-benzoimidazol-1 -sulfonic acid dimethylamide

l-Isopropenyl-3-(l-propyl-lH-benzoimidazol-2-ylmethyl)-l,3-dihydro-imidazo[4,5-c]pyridine-2-one

Bis(5-amidino-2-benzimidazolyl)-methane

2-{2-[1-[1-(2-Amino-ethyl)-piperidin-4-ylamino]-4-methyl-benzoimidazol-1-ylmethyl}-6-methyl-pyridin-3-ol

or a pharmaceutically acceptable salt thereof.

27. (Previously presented) A composition according to claim 1, wherein component (a) is 1-cyclopropyl-3-[1-(4-hydroxy-butyl)-1H-benzoimidazol-2-ylmethyl]-1 ,3-dihydro-imidazo[4,5-c]pyridin-2-one, {2-[2-(1 ,2-dihydro-benzotriazol-1-ylmethyl)-benzoimidazol-1-yl]] ethyl}-diethyl-amine, {2-[2-(3-iodo-2,3-dihydro-indazol-l-ylmethyl)-benzimidazol-l-yl]-ethyl}-dimethyl-amine or a pharmaceutically acceptable salt thereof.

28. (Previously presented) A composition according to claim 1, wherein component (a) is 1-cyclopropyl-3-[1-(4-hydroxy-butyl)-1H-benzoimidazol-2-ylmethyl]-1,3-dihydro-imidazo[4,5-c]pyridin-2-one or l-Isopropenyl-3-(l-propyl-lH-benzoimidazol-2-ylmethyl)-1,3-dihydro-imidazo[4,5-c]pyridine-2-one or a pharmaceutically acceptable salt thereof.

29. (Previously presented) A composition according to claim 1, wherein component (a) is present in an amount of from 0.025 wt% to 10 wt%.

30. (Previously presented) A composition according to claim 1, wherein component (b) is present in an amount of 0.025 wt% to 10 wt%.

31. (Previously presented) A composition according to claim 1, for use in the treatment of the human or animal body.

32. (Previously presented) The use of:

(a) an RSV fusion protein inhibitor as defined in claim 1; and

(b) a benzodiazepine derivative defined in claim 1, in the manufacture of a medicament for use in treating or preventing an RSV infection.

33. (Previously presented) The use according to claim 32, wherein component (a) is present in an amount of from 0.025 wt% to 10 wt% and component (b) is present in an amount of 0.025 wt% to 10 wt%.

34. (Previously presented) A product comprising:

(a) an RSV fusion protein inhibitor as defined in claim 1; and

(b) a benzodiazepine derivative as defined claim 1;

for separate, simultaneous or sequential use in the treatment of the human or animal body.

35. (Currently amended) A product according to claim 34 for separate, simultaneous or sequential use in treating ~~or preventing~~ an RSV infection.

36. (Previously presented) A method of treating or preventing an RSV infection in a patient, which method comprises the administration to said patient of:

(a) an RSV fusion protein inhibitor as defined in claim 1; and

(b) a benzodiazepine derivative as defined in claim 1.

37. (Previously presented) The use of an RSV fusion protein inhibitor as defined in claim 1, in the manufacture of a medicament for use in treating or preventing an RSV infection, by co-administration with a benzodiazepine derivative as defined in claim 1.

38. (Previously presented) The use of a benzodiazepine derivative as defined in claim 1, in the manufacture of a medicament for use in treating or preventing an RSV infection, by co-administration with an RSV fusion protein inhibitor as defined in claim 1.

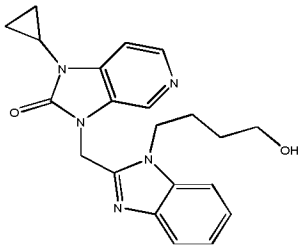
REMARKS

Claims 1-38 were pending in this application. Claims 25, 32, 33 and 36-38 have been previously withdrawn. Claim 23 is herein cancelled and claim 1 is amended to incorporate the limitations of previous claim 23. Claim 24 is also amended herein. Upon entrance of the present amendment, claims 1-22 and 24-38 will remain pending. *No new matter has been added.*

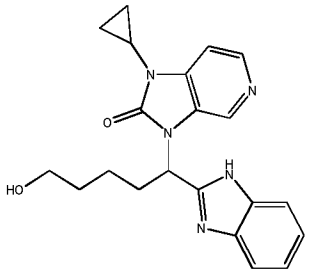
Claim Rejections Under 35 U.S.C. § 103(a)

Claims 1-24, 26-31 and 34-45 stand rejected under 35 U.S.C. § 103(a) on the basis that they are unpatentable over WO 2001/95910 (hereinafter "Yu *et al.*") in view of WO 2004/026843 (hereinafter "Carter *et al.*"). Particularly, it is asserted that Yu *et al.* teaches compounds which are effective for treatment of the respiratory Syncytial virus. It is further asserted that Yu *et al.* discloses compounds such as 1-cyclopropyl-1,3-dihydro-3-[[1-(4-hydroxybutyl)-1H-benzimidazol-2-yl]methyl]-2H-imidazo[4,5-c]pyridine-2-one at Example 73 of Yu *et al.* and that the cyclopropyl group in said compound can be replaced by an isopropenyl group. It is further asserted that since Yu *et al.* teaches that the compounds are present in compositions with pharmaceutically acceptable carriers and that the compounds inhibit RSV, it would have been expected that the RSV fusion protein associated with the virus would have been inhibited. Applicant respectfully disagrees.

First, for completeness of the record, Applicant reiterates that the compound disclosed in Example 73 of Yu *et al.*



is in fact 1-cyclopropyl-3-((1-(4-hydroxybutyl)-1H-benzo[d]imidazol-2-yl)methyl)-1H-imidazo[4,5-c]pyridin-2(3H)-one and *is not* 1-cyclopropyl-3-[1-(4-hydroxybutyl)-1H-benzoimidazol-2-ylmethyl]-1,3-dihydro-imidazo[4,5-c]pyridine-2-one.



Nonetheless, for purposes of this discussion, the compound in Example 73 will be referred to as 1-cyclopropyl-3-[1-(4-hydroxybutyl)-1H-benzoimidazol-2-ylmethyl]-1,3-dihydro-imidazo[4,5-c]pyridine-2-one.

Applicant further submits that Yu *et al.* does not disclose the compounds of the present invention that represent component (a) of claim 1. The compound disclosed by Example 73 of Yu *et al.* includes a hydroxybutyl group extending from the benzoimidazol group. Moreover, the compounds of Yu *et al.* and specifically the compound of Example 73 do not allow a hydroxybutyl substitution at the carbon located between the benzoimidazol group and the imidazo-pyridine group. Applicant submits that this is quite contrary to compounds of component (a) and also contrary to the elected specie of component (a) (i.e., ***1-isopropenyl-3-(1-propyl-1H-benzoimidazol-2-ylmethyl)-1,3-dihydro-imidazo[4,5-c]pyridine-2-one***) which do not allow a hydroxybutyl substitution on the benzoimidazol group while allowing a hydroxybutyl substitution to the carbon located between the benzoimidazol group and the imidazo-pyridine group. Accordingly, Applicant respectfully submits that it would not be possible to substitute an isopropenyl moiety for the cyclopropyl moiety on the imidazo-pyridine group and obtain the elected specie of component (a) as suggested in the office action. Applicant therefore submits that Yu *et al.* does not disclose the compounds of component (a) and therefore could not have disclosed that they are suitable for use in treating RSV or inhibiting the RSV fusion protein.

It is further asserted in the office action that Yu *et al.* is deficient because it does not explicitly teach that the composition further comprises a benzodiazepine derivative capable of inhibiting RSV replication. To cure this deficiency, it is asserted in the office action that Carter *et al.* teaches benzodiazepines and the elected specie of component (b) which are effective for inhibiting RSV replication. It is also asserted that Carter *et al.* teaches that the benzodiazepines can be in a composition with acceptable carriers and that the benzodiazepines can be combined

with other anti-viral compounds. It is further asserted that one of ordinary skill in the art, would have been motivated to combine (a) an inhibitor of the RSV fusion protein of formula (I) as taught by Yu *et al.* with (b) a benzodiazepine inhibitor of formula (V) as taught by Carter *et al.* because both components (a) and (b) are taught as being effective for treating and inhibiting RSV. Applicant respectfully disagrees.

As discussed above, Yu *et al.* does not disclose the compounds of component (a) of claim 1 and therefore does not teach that the compounds of component (a) can be used to inhibit the RSV fusion protein. Moreover, Applicant submits that there are numerous anti-viral compounds and neither Yu *et al.* nor Carter *et al.* teaches or suggests the combination of benzodiazepines with the compounds of component (a) or the elected specie of compound (a).

In view of the above amendments and discussion, Applicant submits that neither Yu *et al.* nor Carter *et al.* teaches or suggests 1-isopropenyl-3-(1-propyl-1H-benzoimidazol-2-ylmethyl)-1,3-dihydro-imidazo[4,5-c]pyridine-2-one or that it is suitable as an inhibitor of the RSV fusion protein. Moreover, neither Carter *et al.* nor Yu *et al.* teaches or suggests that benzodiazepines can be combined with the compounds of component (a) of claim 1 or the elected specie of component (a). Accordingly, neither of the cited references, alone or in combination, teaches or suggests each element of the claimed invention and therefore fails to render the claimed invention obvious.

Applicant therefore respectfully requests reconsideration and withdrawal of the outstanding obviousness rejections.

Claim Rejections - Obviousness Type Double Patenting

Claims 1-8, 12, 16-19, 23, 24, 26, 29-31 and 34 are provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-4, 7-8, 23-24, 29-31 and 34 of copending Application No. 10/593,382.

Applicant notes that the foregoing rejections are provisional in nature and respectfully submit that they will be further addressed when appropriate, i.e., when the non-statutory

obviousness-type double patenting rejection is the only rejection remaining in the later-filed application (MPEP § 804 I(B)).

Conclusion

It is Applicant's understanding that no fees other than the fees indicated in the accompanying fee transmittal is due with the filing of this response. However, should any additional fees be necessary, the Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 50-4876, under Order No. 117750-01801.

If a telephone conversation with Applicant's attorney would help expedite the prosecution of the above-identified application, the Examiner is urged to call the undersigned attorney at (617) 449-6500.

Dated: September 13, 2010

Respectfully submitted,

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